

AUG 28 2000

K001960

BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology

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**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS****FOR****BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology****1. SUBMITTER INFORMATION:**

Polymer Technology  
Global Vision Care  
1400 N. Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450

**2. CONTACT PERSON:**

Debra L.B. Ketchum  
Manager, Regulatory Affairs  
Address: 1400 North Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450  
Telephone No.: (716) 338-8638  
Fax No.: (716) 338-0702  
E-mail Address: dketchum@bausch.com

**3. DEVICE IDENTIFICATION:**

Classification Name: Rigid Gas Permeable (hydrophobic) Contact Lens

Proprietary Name: BOSTON XO (hexafocon A) Contact Lens  
for Orthokeratology

Common Name: Fluoro silicone acrylate rigid gas permeable contact lens  
material

**4. PREDICATE DEVICE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is substantially equivalent to the currently marketed CONTEX OK (siflufacon A) Rigid Gas Permeable Contact Lens for Orthokeratology, which was cleared on April 8, 1998 in 510(k) Premarket Notification No. K973697.

**5. DESCRIPTION OF THE DEVICE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is composed of aliphatic fluoroitaconate siloxanyl methacrylate copolymer.

The color additives conform to 21 CFR Part 74.3206 (green) and 21 CFR Part 74.1602 (violet). The hexafocon A material has an oxygen permeability (Dk) of 100, a specific gravity of 1.27, and the lens visible light transmittance of at least 70%. The hexafocon A name has been adopted by the United States Adopted Names Council (USAN)

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is a rigid gas permeable contact lens in a reverse geometry design. The lens material, which is hexafocon A, is a fluoro silicone acrylate material.

**6. INDICATIONS FOR USE:**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters in non-diseased eyes. The lens may be disinfected using a chemical disinfection system only. Note: To maintain the orthokeratology effect of myopia reduction lens wear must be continued on a prescribed wearing schedule.

**7. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE:**

The safety and efficacy of *BOSTON XO (hexafocon A) Contact Lens Material* was demonstrated in 510(k) Premarket Notification No. K000795, cleared on May 26, 2000. Also, the use of a rigid gas permeable contact lens in a daily wear orthokeratology program for temporary reduction of myopia of up to 3.00 diopters was approved in the CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology 510(k) Premarket Notification No. K973697, cleared on April 8, 1998.

**8. SUBSTANTIAL EQUIVALENCE**

The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is substantially equivalent to the currently marketed CONTEX OK (siflufocon A) Rigid Gas Permeable Contact Lens for Orthokeratology, which was cleared on April 8, 1998 in 510(k) Premarket Notification No. K973697.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 28 2000

Ms. Debra L.B. Ketchum  
Manager, Regulatory Affairs  
Polymer Technology  
1400 North Goodman Street  
P.O. Box 30450  
Rochester, New York 14603-0450

Re: K001960

Trade Name: BOSTON XO (hexafocon A) Contact Lens for Orthokeratology (Daily Wear)

Regulatory Class: II

Product Code: 86 HQD, MUW

Dated: July 26, 2000

Received: July 27, 2000

Dear Ms. Ketchum:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

The safety and effectiveness of this device when worn overnight in an orthokeratology fitting and maintenance program have not been established.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation

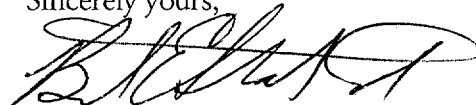
may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "B. Statland", written over a horizontal line.

Bernard E. Statland, M.D., Ph.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Polymer Technology  
1400 North Goodman Street  
P.O. Box 450  
Rochester, New York 14603-0450

**INDICATIONS FOR USE STATEMENT:**

510 (k) number (if known) K001960

Device Name: BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology

**Indications For Use:**

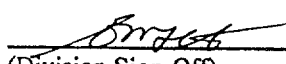
The *BOSTON XO (hexafocon A) RGP Contact Lens for Orthokeratology* is indicated for daily wear in an orthokeratology fitting program for the temporary reduction of myopia of up to 3.00 diopters in non-diseased eyes. The lens may be disinfected using a chemical disinfection system only.

Note: To maintain the orthokeratology effect of myopia reduction lens wear must be continued on a prescribed wearing schedule.

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, office of Device Evaluation (ODE)

Prescription use ☒ or Over the Counter Use ☐

  
(Division Sign-Off)  
Division of Ophthalmic Devices

510(k) Number K001960

